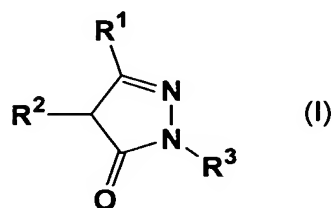


## CLAIMS

[1] A medicament for treating amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or suppressing the progression thereof, which is administered under the condition that a drug holiday period of 1 day or more is provided once or twice during the period for treating the disease or suppressing the progression of the disease, and which comprises as an active ingredient a pyrazolone derivative represented by the following formula (I) or a physiologically acceptable salt thereof, or a hydrate thereof or a solvate thereof:

[Chem.1]



wherein R<sup>1</sup> represents a hydrogen atom, aryl, C<sub>1-5</sub> alkyl, or C<sub>3-6</sub> (total carbon number) alkoxy carbonyl alkyl, R<sup>2</sup> represents a hydrogen atom, aryloxy, arylthio, C<sub>1-5</sub> alkyl or C<sub>1-3</sub> hydroxyalkyl, or R<sup>1</sup> and R<sup>2</sup> are combined with each other to represent C<sub>3-5</sub> alkylene group, and R<sup>3</sup> represents a hydrogen atom, C<sub>1-5</sub> alkyl, C<sub>5-7</sub> cycloalkyl, C<sub>1-3</sub> hydroxyalkyl, benzyl, naphthyl or phenyl, or phenyl substituted with the same or different 1 to 3 substituents selected from the group consisting of C<sub>1-5</sub> alkoxy, C<sub>1-3</sub> hydroxyalkyl, C<sub>2-5</sub> (total carbon number) alkoxy carbonyl, C<sub>1-3</sub> alkylthio, C<sub>1-4</sub> alkylamino, C<sub>2-8</sub> (total carbon number) dialkylamino, halogen atom, trifluoromethyl, carboxyl, cyano, hydroxyl group, nitro, amino and acetamide.

[2] The medicament of claim 1, wherein the pyrazolone derivative is 3-methyl-1-phenyl-2-pyrazoline-5-on.

[3] The medicament of claim 1 or 2, wherein the drug holiday period is provided after a drug administration period of about 7 to 14 days.

[4] The medicament of any one of claims 1 to 3, wherein a second or subsequent drug administration period is about 5 to 14 days.

[5] The medicament of any one of claims 1 to 4, wherein the drug holiday period is

about 14 to 16 days.

[6] The medicament of any one of claims 1 to 5, wherein the drug administration period and the drug holiday period are each 14 days.

[7] The medicament of claim 1 or 2, wherein a course consisting of an initial drug administration period of 14 days and a drug holiday period of 14 days is provided, followed by repetitions of the following combination of periods:

drug administration period: 5 days per week for 2 weeks; and

drug holiday period: 14 days.

[8] The medicament of any one of claims 1 to 7, wherein the daily dose contains about 15 to 240 mg of a pyrazolone derivative as an active ingredient, or about 15 to 240 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

[9] The medicament of any one of claims 1 to 8, wherein the daily dose contains about 60 mg of a pyrazolone derivative as an active ingredient, or about 60 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

[10] The medicament of any one of claims 1 to 9, wherein the administration is carried out once daily.

[11] The medicament of any one of claims 1 to 10, wherein the administration is a continuous administration.

[12] The medicament of claim 11, wherein the continuous administration is intravenous infusion administration.

[13] The medicament of claim 12, wherein the administration rate in the intravenous infusion administration is about 0.5 to 1 mg/minute with respect to a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient.

[14] The medicament of claim 11, wherein the continuous administration is an administration form that is substantially equivalent to the intravenous infusion

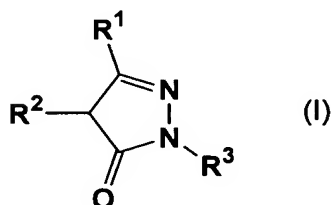
administration wherein the amount of a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient administered per minute is about 0.5 to 1 mg.

[15] The medicament of any one of claims 1 to 14 wherein the symptoms caused by amyotrophic lateral sclerosis are decreased respiratory function, voice and speech disorders, dysphagia, or upper and lower extremity motor disorders.

[16] The medicament of any one of claims 1 to 14 wherein the treatment of amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or the suppression of the progression thereof is a suppression of decrease in respiratory function in amyotrophic lateral sclerosis.

[17] A method for administering as an active ingredient a pyrazolone derivative represented by the following formula (I) or a physiologically acceptable salt thereof, or a hydrate thereof or a solvate thereof, for treating amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or suppressing the progression thereof, wherein a drug holiday period of 1 day or more is provided once or twice during the period for treating the disease or suppressing the progression of the disease,

[Chem.2]



wherein  $R^1$  represents a hydrogen atom, aryl,  $C_{1-5}$  alkyl, or  $C_{3-6}$  (total carbon number) alkoxyalkyl,  $R^2$  represents a hydrogen atom, aryloxy, arylthio,  $C_{1-5}$  alkyl or  $C_{1-3}$  hydroxyalkyl, or  $R^1$  and  $R^2$  are combined with each other to represent  $C_{3-5}$  alkylene group, and  $R^3$  represents a hydrogen atom,  $C_{1-5}$  alkyl,  $C_{5-7}$  cycloalkyl,  $C_{1-3}$  hydroxyalkyl, benzyl, naphthyl or phenyl, or phenyl substituted with the same or different 1 to 3 substituents selected from the group consisting of  $C_{1-5}$  alkoxy,  $C_{1-3}$  hydroxyalkyl,  $C_{2-5}$  (total carbon number) alkoxyalkyl,  $C_{1-3}$  alkylthio,  $C_{1-4}$  alkylamino,  $C_{2-8}$  (total carbon number) dialkylamino, halogen atom, trifluoromethyl, carboxyl, cyano, hydroxyl group, nitro, amino and acetamide.

[18] The method for administration of claim 17, wherein the pyrazolone derivative is 3-methyl-1-phenyl-2-pyrazoline-5-on.

[19] The method for administration of claim 17 or 18, wherein the drug holiday period is provided after a drug administration period of about 7 to 14 days.

[20] The method for administration of any one of claims 17 to 19, wherein a second or subsequent drug administration period is about 5 to 14 days.

[21] The method for administration of any one of claims 17 to 20, wherein the drug holiday period is about 14 to 16 days.

[22] The method for administration of any one of claims 17 to 21, wherein the drug administration period and the drug holiday period are each 14 days.

[23] The method for administration of claim 17 or 18, wherein a course consisting of an initial drug administration period of 14 days and a drug holiday period of 14 days is provided, followed by repetitions of the following combination of periods:

drug administration period: 5 days per week for 2 weeks; and

drug holiday period: 14 days.

[24] The method for administration of any one of claims 17 to 23, wherein the daily dose contains about 15 to 240 mg of a pyrazolone derivative as an active ingredient, or about 15 to 240 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

[25]. The method for administration of any one of claims 17 to 24, wherein the daily dose contains about 60 mg of a pyrazolone derivative as an active ingredient, or about 60 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

[26] The method for administration of any one of claims 17 to 25, wherein the administration is carried out once daily.

[27] The method for administration of any one of claims 17 to 26, wherein the administration is a continuous administration.

[28] The method for administration of claim 27, wherein the continuous

administration is intravenous infusion administration.

[29] The method for administration of claim 28, wherein the administration rate in the intravenous infusion administration is about 0.5 to 1 mg/minute with respect to a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient.

[30] The method for administration of claim 27, wherein the continuous administration is an administration form that is substantially equivalent to the intravenous infusion administration wherein the amount of a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient administered per minute is about 0.5 to 1 mg.

[31] The method for administration of any one of claims 17 to 30 wherein the symptoms caused by amyotrophic lateral sclerosis are decreased respiratory function, voice and speech disorders, dysphagia, or upper and lower extremity motor disorders.

[32] The method for administration of any one of claims 17 to 30 wherein the treatment of amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or the suppression of the progression thereof is a suppression of decrease in respiratory function in amyotrophic lateral sclerosis.